



Attorney's Docket No.: 07039-280001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Robert Simari
Serial No. : 09/980,525
Filed : November 15, 2001
Title : ADENOVIRUS VECTORS ENCODING BRAIN NATRIURETIC PEPTIDE

Art Unit : Unknown
Examiner : Unknown

Commissioner for Patents
Washington, D.C. 20231

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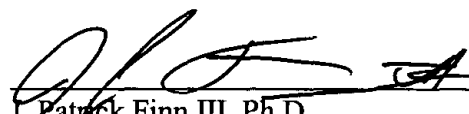
INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO-1449, copies of which are enclosed. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

This statement is being filed within three months of the filing date of the application or before the receipt of a first Office action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: June 3, 2002


J. Patrick Finn III, Ph.D.
Reg. No. 44,109

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

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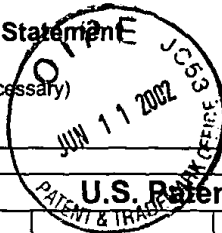
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 07039-280001	Application No. 09/980,525
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Robert Simari	
		Filing Date November 15, 2001	Group Art Unit Unknown



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U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,051,842	10/04/77	Hazel et al.			
	AB	4,140,122	02/20/79	Kühl et al.			
	AC	4,383,529	05/17/83	Webster			
	AD	5,560,922	10/01/96	Chien et al.			
	AE	5,580,859	12/03/96	Felgner et al.			
	AF	5,848,956	12/15/98	Grettner			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AG	0 533 084 A1	03/24/93	EPO				
	AH	0 911 034 A1	04/28/99	EPO				
	AI	WO 93/02556	02/18/93	PCT				
	AJ	WO 99/12576	03/18/99	PCT				
	AK	WO 00/71576	11/30/00	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AL	Abdallah et al., "Non-viral gene transfer: Applications in developmental biology and gene therapy," <u>Biol. Cell</u> , 1995, 85:1-7
	AM	Adelman et al., "In Vitro Deletional Mutagenesis for Bacterial Production of the 20,000-Dalton Form of Human Pituitary Growth Hormone," <u>DNA</u> , 1983, 2(3):183-193
	AN	Amin et al., "Differential Mechanisms of Action of Atrial Natriuretic Peptide (ANP) and C-Type Natriuretic Peptide (CNP) on Juxtamedullary Afferent Arteriole," <u>JASN</u> , 1995, 6:654 - Abstract No. 1296
	AO	Barker and Dayhoff, "Detecting Distant Relationships: Computer Methods and Results," <u>Atlas of Protein Sequence and Structure</u> , 1972, Volume 5, National Biomedical Research Foundation, Chapter 10, pp. 101-110
	AP	Baumgartner et al., "Clinical Evidence that Vascular Endothelial Growth Factor Enhance Vascular Permeability," <u>Circulation (Suppl.)</u> , 1997, 96(8):I-4 - Abstract No. 21
	AQ	Bonow, "New Insights Into the Cardiac Natriuretic Peptides," <u>Circulation</u> , 1996, 93:1946-1950
	AR	Burnett, Jr. et al., "Effects of synthetic atrial natriuretic factor on renal function and renin release," <u>Am. J. Physiol.</u> , 1984, 247(5, Part 1 of 2):F863-F866
	AS	Burnett, Jr. et al., "Atrial Natriuretic Peptide Elevation in Congestive Heart Failure in the Human," <u>Science</u> , 1986, 231:1145-1147

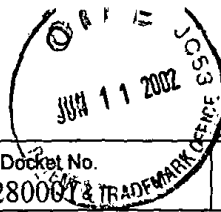
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Other Documents (include Author, Title, Date, and Place of Publication)

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	AT	Caplice et al., "Expression and Regulation of Tissue Factor Pathway Inhibitor in Arteries and Vascular Smooth Muscle Cells," <u>Circulation (Suppl.)</u> , 1997, 96(8):I-663 - Abstract No. 3707
	AU	Chaumet-Riffaud et al., "Altered PGE ₂ and PGF _{2α} production by glomeruli and papilla of sodium-depleted and sodium-loaded rats," <u>Am. J. Physiol.</u> , 1981, 241(4):F517-F524
	AV	Chowdhury et al., "Long-Term Improvement of Hypercholesterolemia After ex Vivo Gene Therapy in LDLR-Deficient Rabbits," <u>Science</u> , 1991, 254:1802-1805
	AW	Cody et al., "Atrial Natriuretic Factor in Normal Subjects and Heart Failure Patients," <u>J Clin. Invest.</u> , 1986, 78:1362-1374
	AX	Crea et al., "Chemical synthesis of genes for human insulin," <u>Proc. Natl. Acad. Sci. USA</u> , 1978, 75(12):5765-5769
	AY	Davis et al., "Direct Gene Transfer into Skeletal Muscle <i>In Vivo</i> : Factors Affecting Efficiency of Transfer and Stability of Expression," <u>Human Gene Therapy</u> , 1993, 4:151-159
	AZ	Davis et al., "Plasmid DNA Is Superior to Viral Vectors for Direct Gene Transfer into Adult Mouse Skeletal Muscle," <u>Human Gene Therapy</u> , 1993, 4:733-740
	AAA	Dayhoff, "Survey of New Data and Computer Methods of Analysis," <u>Atlas of Protein Sequence and Structure</u> , 1976, Volume 5, Supplement 2, National Biomedical Research Foundation, pp. 1-8
	ABB	de Bold et al., "A Rapid and Potent Natriuretic Response to Intravenous Injection of Atrial Myocardial Extract in Rats," <u>Life Sciences</u> , 1981, 28:89-94
	ACC	de Bold et al., "Mechanical and neuroendocrine regulation of the endocrine heart," <u>Cardiovasc. Res.</u> , 1996, 31:7-18
	ADD	Donnelly et al., "Protective Efficacy of Intramuscular Immunization with Naked DNA," <u>Ann. N.Y. Acad. Sci.</u> , 1995, 772:40-46
	AEE	Edwards et al., "Identification of Atrial Natriuretic Factor within Ventricular Tissue in Hamsters and Humans with Congestive Heart Failure," <u>J. Clin. Invest.</u> , 1988, 81:82-86
	AFF	Erllich (ed.), <u>PCR Technology - Principles and Applications for DNA Amplification</u> , 1989, M Stockton Press, New York (Table of Contents only)
	AGG	Field et al., "Kidney function in ANF-transgenic mice: effect of blood volume expansion," <u>Am. J. Physiol.</u> , 1991, 260(1, Part 2 of 2):R1-R5
	AHH	Fraenkel et al., "Sodium status affects GC-B natriuretic peptide receptor mRNA levels, but not GC-A or C receptor mRNA levels, in the sheep kidney," <u>Clin. Sci.</u> , 1994, 86:517-522
	AII	Gardner et al., "Molecular Biology of the Natriuretic Peptides," <u>Trends Cardiovasc. Med.</u> , 1994, 4(4):159-165
	AJJ	Giordano et al., "Intracoronary gene transfer of fibroblast growth factor-5 increases blood flow and contractile function in an ischemic region of the heart," <u>Nature Medicine</u> , 1996, 2(5):534-539
	AKK	Goeddel et al., "Synthesis of human fibroblast interferon by E. coli," <u>Nucleic Acids Res.</u> , 1980, 8(18):4057-4074
	ALL	Grantham et al., "BNP: pathophysiological and potential therapeutic roles in acute congestive heart failure," <u>Am. J. Physiol.</u> , 1997, 272(4, Part 2 of 2):R1077-R1083
	AMM	Guzman et al., "Efficient Gene Transfer Into Myocardium by Direct Injection of Adenovirus Vectors," <u>Circ. Res.</u> , 1993, 73:1202-1207
	ANN	Hunt et al., "The Amino-Terminal Portion of Pro-Brain Natriuretic Peptide (Pro-BNP) Circulates in Human Plasma," <u>Biochem. Biophys. Res. Comm.</u> , 1995, 214(3):1175-1183

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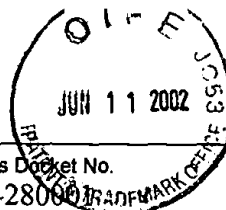
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		Applicant Robert Simari	
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		Information Disclosure Statement by Applicant (Use several sheets if necessary)	

(37 CFR §1.98(b))

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AOO	Isner et al. "Arterial Gene Therapy for Therapeutic Angiogenesis in Patients With Peripheral Artery Disease," <u>Circulation</u> , 1995, 91:2687-2692
	APP	John et al., "Genetic Decreases in Atrial Natriuretic Peptide and Salt-Sensitive Hypertension," <u>Science</u> , 1995, 267:679-681
	AQQ	Kantor et al., "Systemic and Myocardial Expression of Brain Natriuretic Peptide After Adenoviral-Mediated Gene Transfer Using a New Catheter-Based Approach," <u>J. Am. Col. Cardiol.</u> , 2000, 35(2 - Suppl. A):234A, Abstract No. 1206-144
	ARR	Kass-Eisler et al., "Quantitative determination of adenovirus-mediated gene delivery to rat cardiac myocytes <i>in vitro</i> and <i>in vivo</i> ," <u>Proc. Natl. Acad. Sci. USA</u> , 1993, 90:11498-11502
	ASS	Koller et al., "Selective Activation of the B Natriuretic Peptide Receptor by C-Type Natriuretic Peptide (CNP)," <u>Science</u> , 1991, 252:120-123
	ATT	Lawn et al., "The sequence of human serum albumin cDNA and its expression in <i>E. coli</i> ," <u>Nucleic Acids Res.</u> , 1981, 9(22):6103-6114
	AUU	Lee et al., "Role of Endogenous Atrial Natriuretic Factor in Acute Congestive Heart Failure," <u>J. Clin. Invest.</u> , 1989, 84:1962-1966
	AVV	Lin et al., "Expression of Recombinant Genes in Myocardium In Vivo After Direct Injection of DNA," <u>Circulation</u> , 1990, 82:2217-2221
	AWW	Lin et al., "Human Atrial Natriuretic Peptide Gene Delivery Reduces Blood Pressure in Hypertensive Rats," <u>Hypertension</u> , 1995, 26(Part 1):847-853
	AXX	Lin et al., "Atrial Natriuretic Peptide Gene Delivery Attenuates Hypertension, Cardiac Hypertrophy, and Renal Injury in Salt-Sensitive Rats," <u>Human Gene Therapy</u> , 1998, 9:1429-1438
	AYY	Lopez et al., "Salt-resistant hypertension in mice lacking the guanylyl cyclase-A receptor for atrial natriuretic peptide," <u>Nature</u> , 1995, 378:65-68
	AZZ	Luchner et al., "Angiotensin II in the Evolution of Experimental Heart Failure," <u>Hypertension</u> , 1996, 28:472-477
	AAAA	Manthorpe et al., "Gene Therapy by Intramuscular Injection of Plasmid DNA: Studies on Firefly Luciferase Gene Expression in Mice," <u>Human Gene Therapy</u> , 1993, 4:419-431
	ABBB	Marcus et al., "Hemodynamic and Renal Excretory Effects of Human Brain Natriuretic Peptide Infusion in Patients With Congestive Heart Failure," <u>Circulation</u> , 1996, 94:3184-3189
	ACCC	Mattingly et al., "Presence of C-type natriuretic peptide in human kidney and urine," <u>Kidney International</u> , 1994, 46:744-747
	ADDD	McDonagh et al., "Symptomatic and asymptomatic left-ventricular systolic dysfunction in an urban population," <u>Lancet</u> , 1997, 350:829-833
	AEEE	Mölling, "Naked DNA for vaccine or therapy," <u>J. Mol. Med.</u> , 1997, 75:242-246
	AFFF	Moore, <u>Current Protocols in Molecular Biology</u> , 1998, Ausubel (ed.), John Wiley & Sons, Inc., New York, pp. 8.2.8 - 8.2.13
	AGGG	Morishita et al., "Autocrine and Paracrine Effects of Atrial Natriuretic Peptide Gene Transfer on Vascular Smooth Muscle and Endothelial Cellular Growth," <u>J. Clin. Invest.</u> , 1994, 94:824-829
	AHHH	Mukoyama et al., "Brain Natriuretic Peptide as a Novel Cardiac Hormone in Humans," <u>J. Clin. Invest.</u> , 1991, 87:1402-1412
	AIII	Mullis et al., "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," <u>Cold Spring Harbor Symposia on Quantitative Biology</u> , 1986, Volume LI, Cold Spring Harbor Laboratory, New York, pp. 263-273

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Sheet 5 of 6

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		Applicant Robert Simari	
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**Information Disclosure Statement
by Applicant**

(Use several sheets if necessary)

(37 CFR §1.98(b))

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	ACCCC	Sawada et al., "Stretch-induced Hypertrophic Growth of Cardiocytes and Processing of Brain-type Natriuretic Peptide Are Controlled by Proprotein-processing Endoprotease Furin," <u>J. Biol. Chem.</u> , 1997, 272(33):20545-20554
	ADDDD	Schirger et al., "Antiproliferative and Vasodilating Actions of BNP: Modulation by Atherosclerosis and NEP Inhibition," <u>Circulation (Suppl.)</u> , 1998, 98(17 Suppl.):I598-I599, Abstract No. 3144
	AEEEE	Schirger et al., "Presence of <i>Dendroaspis</i> Natriuretic Peptide-Like Immunoreactivity in Human Plasma and Its Increase During Human Heart Failure," <u>Mayo Clin. Proc.</u> , 1999, 74:126-130
	AFFFF	Schocken et al., "Prevalence and Mortality Rate of Congestive Heart Failure in the United States," <u>JACC</u> , 1992, 20(2):301-306
	AGGGG	Seilhamer et al. "Human and Canine Gene Homologs of Porcine Brain Natriuretic Peptide," <u>Biochem. Biophys. Res. Comm.</u> , 1989, 165(2):650-658
	AHHHH	Simari et al., <u>Current Protocols in Human Genetics</u> , 1996, John Wiley & Sons, New York, Sections 13.1.1 - 13.1.10
	AIIII	Simari et al., "Regulation of Cellular Proliferation and Intimal Formation following Balloon Injury in Atherosclerotic Rabbit Arteries," <u>J. Clin. Invest.</u> , 1996, 98:225-235
	AJJJJ	Simari et al., "Requirements for Enhanced Transgene Expression by Untranslated Sequences from the Human Cytomegalovirus Immediate-Early Gene," <u>Mol. Med.</u> , 1998, 4:700-706
	AKKKK	Smith and Waterman, "Comparison of Biosequences," <u>Advances in Applied Mathematics</u> , 1981, 2:482-489
	ALLLL	SOLVD Investigators, "Effect of Enalapril on Survival in Patients with Reduced Left Ventricular Ejection Fractions and Congestive Heart Failure," <u>N. Engl. J. Med.</u> , 1991, 325(5):293-302
	AMMMM	Stein et al., "Natriuretic peptides: Physiology, therapeutic potential, and risk stratification in ischemic heart disease," <u>Am. Heart J.</u> , 1998, 135:914-923
	ANNNN	Steiner et al. "Radioimmunoassay for Cyclic Nucleotides," <u>J. Biol. Chem.</u> , 1972, 247(4):1106-1113
	AOOOO	Steinhilper et al., "Hypotension in Transgenic Mice Expressing Atrial Natriuretic Factor Fusion Genes," <u>Hypertension</u> , 1990, 16:301-307
	APPPP	Stephan et al., "A New Cationic Liposome DNA Complex Enhances the Efficiency of Arterial Gene Transfer <i>In Vivo</i> ," <u>Human Gene Therapy</u> , 1996, 7:1803-1812
	AQQQQ	Stevens et al., "Modulation of Exogenous and Endogenous Atrial Natriuretic Peptide by a Receptor Inhibitor," <u>Hypertension</u> , 1994, 23:613-618
	ARRRR	Stevens et al., "A Functional Role for Endogenous Atrial Natriuretic Peptide in a Canine Model of Early Left Ventricular Dysfunction," <u>J. Clin. Invest.</u> , 1995, 95:1101-1108
	ASSSS	Stevens et al., "A Modified Model of Tachycardia-Induced Cardiomyopathy: Insights into Humoral and Renal Adaptations," <u>Pathophysiology of Tachycardia-Induced Heart Failure</u> , Spinale (ed.), 1996, Futura Publishing Company, Inc., Armonk, New York, pp. 133-151
	ATTTT	Stevens et al., "Renal Role of the Endogenous Natriuretic Peptide System in Acute Congestive Heart Failure," <u>J. Cardiac Failure</u> , 1996, 2(2):119-125
	AUUUU	Stevenson et al., "Idiotypic DNA Vaccines Against B-cell Lymphoma," <u>Immunological Reviews</u> , 1995, 145:211-228
	AVVVV	Stingo et al., "Cardiovascular and renal actions of C-type natriuretic peptide," <u>Am. J. Physiol.</u> , 1992, 262(1, Part 2 of 2):H308-H312
	AWWWW	Stingo et al., "Presence of C-type natriuretic peptide in cultured human endothelial cells and plasma," <u>Am. J. Physiol.</u> , 1992, 263(4, Part 2 of 2):H1318-H1321

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Substitute Disclosure Form (PTO-1449)



Sheet 6 of 6

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	AXXXX	Strauss, <u>Current Protocols in Molecular Biology</u> , 1998, Ausugel (ed.), John Wiley & Sons, Inc., New York, Sections 2.2.1 - 2.2.3
	AYYYY	Svensson et al., "Muscle-based gene therapy: realistic possibilities for the future," <u>Mol. Med. Today</u> , 1996, 2(4):166-172
	AZZZZ	Takahashi et al., "Expression of A-, B-, and C-Type Natriuretic Peptide Genes in Failing and Developing Human Ventricles," <u>Circulation Research</u> , 1992, 71:9-17
	AAAAAA	Tateyama et al. "Concentrations and Molecular Forms of Human Brain Natriuretic Peptide in Plasma," <u>Biochem. Biophys. Res. Comm.</u> , 1992, 185(2):760-767
	ABBBB	Tsurumi et al., "Direct Intramuscular Gene Transfer of Naked DNA Encoding Vascular Endothelial Growth Factor Augments Collateral Development and Tissue Perfusion," <u>Circulation</u> , 1996, 94:3281-3290
	ACCCCC	Tripathy et al., "Stable delivery of physiologic levels of recombinant erythropoietin to the systemic circulation by intramuscular injection of replication-defective adenovirus," <u>Proc. Natl. Acad. Sci. USA</u> , 1994, 91:11557-11561
	ADDDDD	Tripathy et al., "Long-term expression of erythropoietin in the systemic circulation of mice after intramuscular injection of a plasmid DNA vector," <u>Proc. Natl. Acad. Sci. USA</u> , 1996, 93:10876-10880
	AEEEE	Tripathy et al., "Immune responses to transgene-encoded proteins limit the stability of gene expression after injection of replication-defective adenovirus vectors," <u>Nature Medicine</u> , 1996, 2(5):545-550
	AFFFFF	Ueno et al., "Local Expression of C-Type Natriuretic Peptide Markedly Suppresses Neointimal Formation in Rat Injured Arteries Through an Autocrine/Paracrine Loop," <u>Circulation</u> , 1997, 96:2272-2279
	AGGGGG	Vieira and Messing, "Production of Single-Stranded Plasmid DNA," <u>Methods in Enzymology</u> , 1987, 153:3-11
	AHHHHH	Vlasuk et al., "Expression and Secretion of Biologically Active Human Atrial Natriuretic Peptide in <i>Saccharomyces cerevisiae</i> ," <u>J. Biol. Chem.</u> , 1986, 261(11):4789-4796
	AIIII	Wei et al., "Natriuretic Peptide System in Human Heart Failure," <u>Circulation</u> , 1993, 88(3):1004-1009
	AJJJJ	Welling et al., "Systemic Delivery of the Interleukin-1 Receptor Antagonist Protein Using a New Strategy of Direct Adenoviral-Mediated Gene Transfer to Skeletal Muscle Capillary Endothelium in the Isolated Rat Hindlimb," <u>Human Gene Therapy</u> , 1996, 7:1795-1802
	AKKKKK	Wolff et al., "Direct Gene Transfer into Mouse Muscle in Vivo," <u>Science</u> , 1990, 247:1465-1468
	ALLLLL	Yang et al., "Developing particle-mediated gene-transfer technology for research into gene therapy of cancer," <u>Mol. Med. Today</u> , 1996, 2:476-481
	MMMMM	Yasue et al., "Localization and Mechanism of Secretion of B-Type Natriuretic Peptide in Comparison With Those of A-Type Natriuretic Peptide in Normal Subjects and Patients With Heart Failure," <u>Circulation</u> , 1994, 90:195-203

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